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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,667

10/27/2003

Paul J. Maddon

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08/04/2009

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

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1643

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,667	Applicant(s) MADDON ET AL.	
	Examiner Stephen L. Rawlings	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,51-53,55,56,59-61,63-90 and 187-265 is/are pending in the application.
- 4a) Of the above claim(s) 197 and 198 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,51-53,55,56,59-61,63-90,187-196 and 199-265 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040929;20051215</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The election without traverse filed April 10, 2009, is acknowledged and has been entered.

Applicant has elected the species of invention, wherein the PSMA protein is a protein comprising amino acids 44-750 of SEQ ID NO: 1 and the pH of the composition is 7; however, as noted below, the requirement to elect a species by identifying the pH of the composition to which the claims are directed has been withdrawn.

Notably Applicant has remarked that at least claims 48, 52, 55, 56, 59-61, 63-90, 187-198, 199 (in part), 200-208, 210, 212-236, 237 (in part), 238-250, 252-258, 259 (in part), and 260-265 read on the elected species of invention.

2. Claims 48, 51-53, 55, 56, 59-61, 63-90, and 187-265 are pending in the application. Claims 197 and 198 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 10, 2009.

3. Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 currently under prosecution.

Information Disclosure Statement

4. The information disclosures filed September 29, 2004, and December 15, 2005, have been considered. An initialed copy of each is enclosed.

Election/Restrictions

5. The requirement to elect a species of the invention in which the claimed composition has one particular pH selected from 6.5, 7, and 7.5 has been

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withdrawn. To that extent the different species of invention presented by the originally filed claims have been rejoined.

Priority

6. Applicant's claim under 35 U.S.C. §§ 119 and/or 120 for benefit of the earlier filing date of Application No. 10/395,894, filed March 21, 2003, which is a continuation-in-part of international application PCT/US02/33944, filed October 23, 2002, and claims benefit of U.S. Provisional Application No. 60/335,215, filed October 23, 2001, U.S. Provisional Application No. 60/362,747, filed March 7, 2002, and U.S. Provisional Application No. 60/412,618, filed September 20, 2002, is acknowledged.

However, the claims do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

There are additional reasons that some or all of the claims do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, namely failure of one or more of the priority documents to provide written support for the language of the claims. Given the number of claims that are presently under prosecution, it is a serious burden to determine which priority documents provide the necessary written support for which of the claims; nonetheless, it is aptly noted, for example, while claim 78 is directed to

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the composition of claim 77, wherein the surfactant is Triton X-100, it appears that prior filed Application No. 10/395,894 and any of the provisional applications fail to disclose such a composition. As another example of similar deficiencies of the priority documents, while claim 74 is directed to the composition of claim 48, wherein the composition further comprises a non-naturally occurring free amino acid, it appears that none of Application No. 10/395,894 and any of the provisional applications describes such a composition. Still other deficiencies of Application No. 10/395,894 and any of the provisional applications have been noted, but have not been listed in the interest of brevity.

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely October 27, 2003.

Drawings

7. The drawing set forth as Figure 13 is objected to because the figure depicts nucleic acid and amino acid sequences, which are not identified by sequence identification numbers, either in the figure or in the brief description of figure at page 27 of the specification. Sequences appearing in the specification and/or drawings must be identified by a sequence identifier in accordance with 37 C.F.R. 1.821(d); sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

A replacement drawing sheet, including the correction, is required, if the drawings are objected to. See 37 CFR 1.121(d). However, this ground of objection would be withdrawn, so that a replacement drawing would be not be required, if Applicant were to amend the brief description of the figure at page 30 of the specification to include sequence identification numbers.

Specification

8. The disclosure is objected to for the following reason: The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Sequences appearing in the specification and/or drawings must be

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identified by sequence identifier in accordance with 37 C.F.R. 1.821(d). According to 37 CFR § 1.821(a), an unbranched sequence of four or more specifically identified amino acids or an unbranched sequence of ten or more nucleotides must be identified by sequence identification numbers. See MPEP § 2422.01.

In this instance, the sequences depicted in Figure 13 are not identified by sequence identification numbers, either in the figure or in the brief description of figure at page 27 of the specification, as filed.

Applicant must provide appropriate amendments to the specification or drawings inserting the required sequence identifiers. Sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required. If necessary to correct the deficiency, Applicant must submit paper and computer-readable copies of a substitute sequence listing, together with an amendment directing its entry into the specification and a statement that the content of both copies are the same and, where applicable, include no new matter.

9. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark appearing in the specification is BiaCore™ (see, e.g., paragraph [0138] of the published application¹).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the

¹ U.S. Patent Application Publication No. 2004/0161776-A1.

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appropriate symbol indicating its proprietary nature (e.g., TM, [®]), and accompanied by generic terminology. Applicants may identify trademarks using the “Trademark” search engine under “USPTO Search Collections” on the Internet at <http://www.uspto.gov/web/menu/search.html>.

10. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

An example of such an impermissible disclosure appearing in the specification is found in paragraph [0177] of the published application.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference. See 37 CFR § 1.57.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 are indefinite for the following reason:

Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 contain the term “PSMA”, which is used as the sole means of identifying the polypeptide to

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which the claims refer. The use of such laboratory designations only to identify a particular polypeptide renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct polypeptides, which are encoded by the same or different genes.

This issue may be remedied by amending the claims to include appropriate reference to the sequence identification number that identifies the amino acid sequence of the polypeptide to which the claims are directed, as set forth in the Sequence Listing of this application. Such an amendment would be remedial because the amino acid sequence of a polypeptide is a unique identifier that unambiguously defines a given polypeptide.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

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These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, “the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention” (*Id.* at 1105). The “Guidelines” continue:

The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsius verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). See also: *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention*.

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In this instance, the claims are directed to a genus of "PSMA proteins" that comprise the amino acid sequence of SEQ ID NO: 1 or a portion thereof.

The specification discloses at paragraph [0013] of the published application the following:

In some embodiments the PSMA protein multimers comprise the full-length PSMA protein (SEQ ID NO: 1) or a fragment thereof. In other embodiments the PSMA protein multimer comprises the extracellular portion of PSMA (amino acids 44-750 of SEQ ID NO: 1) or a fragment thereof. In still other embodiments the PSMA protein multimer comprises the amino acids 58-750 of SEQ ID NO: 1 or a fragment thereof. In yet other embodiments the PSMA protein multimer comprises the amino acids 610-750 of SEQ ID NO: 1 or a fragment thereof. The fragments are capable of forming a PSMA multimer that can be used to generate antibodies that recognize PSMA, preferably native PSMA dimer. Typically, the PSMA multimers are homomultimers, meaning that the two or more PSMA molecules are the same. In other embodiments, the PSMA multimers are heteromultimers, whereby at least two of the PSMA proteins are not the same. In still other embodiments the PSMA proteins can be functionally equivalent proteins, whereby the PSMA protein is conservatively substituted.

Then, at paragraph [0166] of the published application, the specification defines the term "PSMA protein" as inclusive of the full-length PSMA protein (provided as SEQ ID NO: 1) or a portion thereof; and at paragraph [0162] the specification describes the PSMA protein, which is capable of forming multimers, particularly dimers, as inclusive of the full-length protein (SEQ ID NO: 1), the extracellular portion of PSMA (amino acids 44-750 of SEQ ID NO: 1), or an alternatively spliced form of PSMA.

Given these disclosures it is apparent that members of the genus of "PSMA proteins" to which the claims are directed may vary substantially in structure and/or function; however, the genus has not been described in a manner that would permit the skilled artisan to immediately envision, recognize or distinguish its members from others because the members of the genus do not necessarily share any particularly identifying (i.e., substantial) structural feature, which correlates with any one particularly identifying functional feature that is also common among its members.

"Guidelines" states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the

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invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). "Guidelines" further states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (*Id.* at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

Additionally, Applicant is reminded, "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568).

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Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 48, 51, 55, 56, 59, 61, 63, 68, 71-73, 77-90, 196, 250, 251, 253, 254, and 260 are rejected under 35 U.S.C. 102(b) as being anticipated by Grauer et al. (*Cancer Res.* 1998 Nov 1; **58** (21): 4787-4789), as evidenced by Shulke et al. (*Proc. Natl. Acad. Sci. U S A.* 2003 Oct 28; **100** (22):12590-112595).

As evidenced by Shulke et al., LNCaP cellular lysates comprise an isolated dimer of PSMA protein having the sequence of amino acids 44-750 of SEQ ID NO: 1; see entire document (e.g., the abstract).

Grauer et al. teaches a composition comprising lysates of LNCaP cells comprising Triton X-100, magnesium chloride, sodium, and a buffer having a pH of 7.5; see entire document (e.g., the abstract; and page 4787, column 2). Grauer et al. teaches compositions comprising eluents comprising isolated PSMA proteins were prepared by elution in a buffer containing sodium phosphate and 150 mM sodium chloride (page 4787, column 2).

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17. Claims 48, 51-53, 55, 56, 59-61, 63-90, 187-196, and 199-265 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0215472-A1.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Since the effective filing date of this application is deemed October 27, 2003, it is submitted that U.S. Patent Application Publication No. 2005/0215472-A1 is available as prior art under 35 U.S.C. § 102(e), since the publication is an application for patent by another inventive entity, which claims priority to an application having an earlier filing date than the effective filing date of the instant claims.

U.S. Patent Application Publication No. 2005/0215472-A1 (Schulke et al.) teaches a composition comprising an isolated dimer of PSMA, wherein said PSMA comprises the amino acid sequence of SEQ ID NO: 1 and wherein said composition has a pH of 7.0; see entire document (e.g., the abstract; the claims).

Absent a showing of any difference, Schulke et al. teaches a composition that is identical to that to which the instant claims are directed.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 187, 190-193, 208, 209, 212-215, 220, 229, 234, 238, 239, 241, 244, 247-249, 261, and 263-265 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grauer et al. (*Cancer Res.* 1998 Nov 1; **58** (21): 4787-4789), as evidenced by Shulke et al. (*Proc. Natl. Acad. Sci. U S A.* 2003 Oct 28; **100** (22):12590-112595).

As evidenced by Shulke et al., LNCaP cellular lysates comprise an isolated dimer of PSMA protein having the sequence of amino acids 44-750 of SEQ ID NO: 1; see entire document (e.g., the abstract).

Grauer et al. teaches a composition comprising lysates of LNCaP cells comprising Triton X-100, magnesium chloride, sodium, and a buffer having a pH of 7.5; see entire document (e.g., the abstract; and page 4787, column 2).

Grauer et al. however does not expressly teach or suggest the preparation of a lyophilized composition or a kit comprising such composition.

It would have been *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made to have lyophilized the composition in order to store the composition since lyophilization was commonly used at the time as a means for preparing such compositions for long term storage. Furthermore, it would have *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made to have manufactured a kit comprising the composition since the composition and thus the kit comprising the composition could be used in any

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of a variety of different application such as, for example, the production of an antibody that specifically binds to a component of the lysate. Finally, it would have been *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made to have manufactured a kit comprising the composition further comprising a vial to store composition, a diluent to resuspend the lyophilized composition, and/or a syringe, if the vial is comprised of a septum, since the syringe could then be used to penetrate the septum in order to resuspend the lyophilized composition using the diluent. In any event, one ordinarily skilled in the art at the time the invention was made would have been motivated to manufacture such a kit since such kits and their components provide convenience and ease of use, and so are routinely used in the relevant arts.

Conclusion

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

slr
July 31, 2009